

# Consensus on the Prevention of Type 2 Diabetes in Chinese Adults

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## INTRODUCTION

High-risk population of Type 2 diabetes mellitus (T2DM) includes both euglycemic (normal glucose tolerance [NGT]) population with high risk of diabetes (EPWHROD) and prediabetic population. Between these two groups, prediabetic people have a higher chance to develop diabetes. Prediabetes is associated with increased risk of atherosclerotic cerebrocardiovascular disease (ASCCVD), diabetes, microangiopathic diseases, tumors, and dementia.

Present studies have shown that conversion rate from prediabetes to diabetes can be markedly decreased by effective interventions. Early screening and effective management of high-risk populations with NGT and prediabetic populations are fundamental to achieve these results. China has the largest diabetic population in the world, with 92.4 million diabetes. In 2008, 46,239 adults aged 20 or older were recruited by the Chinese Diabetes Society from 14 provinces and municipalities within China (using plasma glucose value as diagnostic criteria published by the World Health Organization). The age-standardized prevalence of diabetes was found to be 9.7%; prevalence of prediabetes was 15.5%. This suggests that over 148.2 million adults in China are in prediabetic condition. The study also showed that the prevalence of total prediabetes was 16.1% in men, including 3.2% impaired fasting glucose/glycemia (IFG), 11.0% impaired glucose tolerance (IGT), and 1.9% IFG combined with IGT. In women, the prevalence of prediabetes was 14.8% and of IFG, IGT, and IFG combined with IGT was 2.2%, 10.9%, and 1.7%, respectively. Among all the prediabetic

individuals, the proportion of IFG, IGT, IFG combined with IGT was 19.9%, 68.3%, 1.8% in men and 14.9%, 73.6%, 11.5% in women, respectively.<sup>[1]</sup> In 2010, an epidemiological study showed the prevalence of prediabetes to be 50.1% in adults over 18 years (using plasma glucose and hemoglobin A1c values as diagnostic criteria published by the American Diabetes Association [ADA]).<sup>[2]</sup> These two large-sample studies although by different diagnostic criteria together indicate that the prevalence of prediabetes is high in China and that one major problem is postload hyperglycemia. Since prediabetes itself causes no obvious clinical manifestations, proactive efforts must be made to spotlight it. Therefore, the Chinese Society of Endocrinology (CSE) has developed a consensus regarding the prevention of type 2 diabetes in Chinese adults.<sup>[3]</sup>

## EVIDENCE LEVEL

The evidence standards of ADA were consulted to develop the following standards of evidence level.<sup>[4]</sup>

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## DEFINITION OF HIGH-RISK POPULATIONS FOR DIABETES

Populations at high risk for diabetes here include both EPWHROD and prediabetic populations.

### Euglycemic (normal glucose tolerance) population with high risk of diabetes

These populations are defined as individuals with a high risk of adult diabetes who have anyone of the following high-risk factors and age over 18 years.

Inclusion criteria: (1) age  $\geq 40$  years; (2) history of prediabetes; (3) overweight status or obesity (body mass index [BMI]  $\geq 24$  kg/m<sup>2</sup>), male waist circumference  $\geq 90$  cm, female waist circumference  $\geq 85$  cm; (4) sedentary lifestyle; (5) family history of T2DM among first-degree relatives; (6) women with history of delivering large babies (macrosomia, birth weight  $\geq 4$  kg), overt diabetes in pregnancy or gestational diabetes mellitus; (7) hypertension (systolic blood pressure  $\geq 140$  mmHg and/or diastolic blood pressure  $\geq 90$  mmHg) or antihypertensive therapy; (8) dyslipidemia (high-density lipoprotein cholesterol  $\leq 0.91$  mmol and triglyceride  $\geq 2.22$  mmol/L or receiving lipid-lowering therapy); (9) ASCCVD; (10) history of steroid diabetes; (11) polycystic ovary syndrome; (12) long-term use of special medications such as glucosteroids and antidepressants.

### Prediabetic populations

Prediabetes is defined as increased fasting plasma glucose (FPG) and/or increased 2 h plasma glucose during oral glucose tolerance testing (OGTT) without meeting the diagnostic criteria for diabetes, including IFG, IGT, and IFG + IGT. Table 1 shows the diagnostic criteria for prediabetes. In this article, the diagnosis of prediabetes as presented in Table 1 was used unless indicated.

## SCREENING OF POPULATION AT HIGH RISK OF DIABETES

People with no history of diabetes were first screened for risk factors (as listed above). Further screening for FPG or random plasma glucose (RPG) should be performed in those who have at least one risk factor during initial screening.

- FPG: FPG  $\geq 5.6$  mmol/L served as a cutoff value for OGTT

Diagnoses	Criterion
IFG	FPG: 5.6–6.9 mmol/L or
IGT	OGTT 2hPG: 7.8–11.0 mmol/L or
IFG + IGT	FPG: 5.6–6.9 mmol/L and OGTT 2hPG: 7.8–11.0 mmol/L

IFG: Impaired fasting glucose/glycemia; IGT: Impaired glucose tolerance; FPG: Fasting plasma glucose; 2hPG: 2 h plasma glucose, OGTT: Oral glucose tolerance testing.

- RPG: RPG  $\geq 7.8$  mmol/L served as a cutoff value for OGTT
- Among elderly individuals, FPG  $< 5.6$  mmol/L and RPG  $< 7.8$  mmol/L cannot completely exclude IGT or postprandial hyperglycemia in diabetes. For this reason, OGTT is recommended to assess glucose metabolism for these aged and other high-risk individuals (such as those diagnosed with coronary heart disease or additional risk factors).

## MANAGEMENT OF POPULATION AT HIGH RISK FOR DIABETES

### Management of euglycemic (normal glucose tolerance) population with high risk of diabetes

- Health education: It currently lacks strong evidence and guidelines regarding the usefulness of health education. With reference to the health education for diabetes, high-risk individuals and/or their families and caregivers ought to receive systematic education, with annual revision. The content of educational materials includes at least relevant information regarding prediabetes and diabetes (e.g., definitions of prediabetes and diabetes, medical nutrition therapy, exercise, and smoking cessation). It also includes information concerning the management of other ASCCVD risks in this population
- Other interventions: (1) Lifestyle intervention is the basis of all interventions. Lifestyle intervention includes medical and nutrition therapy and exercise to reduce the risk of diabetes, obesity and overweight status with the aim of reducing BMI to normal levels (i.e.,  $< 24$  kg/m<sup>2</sup>) or attain a 5–10% weight reduction. Total daily calories are reduced by at least 400–500 kcal and saturated fatty acid intake is limited to  $< 30\%$  of total fatty acid intake. Physical activity time of these persons is increased to 250–300 min per week. Regular follow-up is necessary. (2) Management of other ASCCVD risks, such as blood pressure and blood lipid levels, must be treated as equally important (see control goals section)
- Monitoring: Once initiating lifestyle intervention, blood glucose needs to be monitored regularly. The persons are recommended to have at least one FPG, OGTT test, or both per year.

### Management of prediabetic populations

#### Management of population with impaired fasting glucose/glycemia

- Health education: This is similar to the education given to EPWHROD
- Other interventions: (1) Lifestyle intervention and management of other ASCCVD risks are similar to EPWHROD. Lifestyle intervention is the basis of all other interventions. (2) Antidiabetic drug intervention is recommended for patients with poor blood glucose control (FPG  $> 6.1$  mmol/L) or worsening hyperglycemia despite 6 months of intensive lifestyle

modifications, given that these are young, motivated individuals who are otherwise with good financial status and healthcare accessibility. 750–1700 mg metformin per day is recommended (the average dose of metformin is 2000–2550 mg/d for people who also need to lose weight). For those with metformin intolerance, 150–300 mg acarbose per day (the average dose of acarbose is 300 mg/d for persons who also need to lose weight) or thiazolidinediones (TZDs) such as 4–8 mg rosiglitazone per day or 15–45 mg pioglitazone per day are recommended. Those with heart failure or osteoporosis need to avoid TZDs. All treatment regimens must be in compliance with the principle of individualization or personalization (see section management of special populations)

- Monitoring: Once implementing lifestyle intervention, blood glucose needs to be monitored regularly during follow-up. Moreover, these individuals should undergo at least one FPG, OGTT examination, or both per year. If they had received antidiabetic drug intervention, they were required to undergo FPG examination during each follow-up visit. Regular monitoring of body weight and other ASCCVD risk factors is equally important.

#### Management of population with impaired glucose tolerance

- Health education: It is similar to that given to the EPWHROD
- Other interventions: (1) Lifestyle intervention and management of other ASCCVD risks are similar to that given to the EPWHROD. Again, lifestyle intervention is the cornerstone of all interventions. (2) Antidiabetic drug intervention is recommended for ones with poor blood glucose control (postprandial glucose [PPG] >7.8 mmol/L) or worsening hyperglycemia despite 6 months of intensive lifestyle modifications, given that these are young, motivated individuals who are otherwise with good financial status and healthcare accessibility. Acarbose is recommended (see IFG section). The individuals with acarbose intolerance are prescribed with TZDs (see IFG section)
- Monitoring: PPG is mainly monitored in this population. Blood glucose and other ASCCVD risk factors are monitored in a manner similar to the population with IFG.

#### Management of population with impaired fasting glucose/ glycemia + impaired glucose tolerance

- Health education: It is recommended for this population to receive health education at least once a year
- Other interventions: Intensive lifestyle intervention should implement the same with EPWHROD. Lifestyle intervention also serves as the basis of all other interventions. Early antidiabetic drug intervention is recommended for ones with poor blood glucose control (FPG >6.1 mmol/L and PPG >7.8 mmol/L) or worsening hyperglycemia despite 6 months of intensive lifestyle modifications, given that these are

young, motivated individuals who are otherwise with good financial status and healthcare accessibility. Metformin or acarbose is recommended (see IFG section). Individuals without reaching blood glucose goals despite 6 months of single-drug intervention can be offered combination therapy. Persons with metformin or acarbose intolerance are prescribed TZDs (see IFG section)

- Monitoring: Blood glucose was monitored in this population at least once every 6 months. Indications for monitoring of blood glucose and other ASCCVD risk factors are similar to those used in IGT and IFG patients.

#### Management of special populations

An individualized strategy is performed. The special populations here include prediabetic patients suffering from ASCCVD, older and super-elderly patients, those with Alzheimer's disease, other mental disorders, organ hypofunction, and life expectancy <10 years, and any seniors who lived alone. Due to the large variations in their health and social conditions, these populations only undergo health education and control and monitoring of ASCCVD risk factors other than blood glucose; generally, no specific interventions are performed regarding blood glucose.

#### CONTROL GOALS

##### Glycemic control goals

The CSE consensus emphasizes individualized and personalized strategy. Glycemic control goals are based on their age and life expectancy, presence of microvascular and macrovascular disease, ASCCVD risk factors, and presence of any disease or risk factor resulting in severe hypoglycemia, or social factors (e.g., healthcare accessibility, financial condition, and personal health expectations).

- Ideal level: FPG  $\leq$ 6.1 mmol/L and OGTT 2 h PPG  $\leq$ 7.8 mmol/L. Two-hour common meal PPG <7.8 mmol/L
- The ideal control goal of prediabetic patients is reversing the blood glucose level to NGT. For those whose blood glucose could not be back to NGT, the blood glucose goal is to maintain a prediabetic level to prevent or at least delay progression to diabetes.

##### Body weight control targets

The goal for obese and overweight prediabetic ones is to reduce weight by 5–10% and thereafter maintains a healthy BMI.

##### Control objectives for other atherosclerotic cerebrocardiovascular disease risk factors

In addition to glucose and body weight control, more important goals are management of other ASCCVD risk factors, such as smoking cessation, control of blood pressure and blood lipids [Table 2].

**Table 2: Control goals of ASCVD risk factors other than blood glucose**

Parameter	Control goals
Blood pressure	
SBP	<140 mmHg
DBP	<90 mmHg
Lipid	
LDL-C	Patients with little or no risk of ASCVD: LDL-C $\leq$ 2.6 mmol/L Patients with ASCVD or more than 2 risk factors: LDL-C $\leq$ 1.8 mmol/L
Triglyceride	<2.3 mmol/L
HDL-C	Men >1.0 mmol/L Women >1.3 mmol/L

LDL-C: Low-density lipoprotein cholesterol; HDL-C: High-density lipoprotein cholesterol; ASCVD: Atherosclerotic cerebrocardiovascular disease; SBP: Systolic blood pressure; DBP: Diastolic blood pressure.

## PRIMARY EVIDENCE

Considering word-number restrictions, we will briefly discuss the primary evidence for the consensus.

## EVIDENCE OF DIVIDING PREDIABETIC HYPERGLYCEMIA INTO FASTING GLUCOSE/GLYCEMIA, IMPAIRED GLUCOSE TOLERANCE, AND FASTING GLUCOSE/GLYCEMIA + IMPAIRED GLUCOSE TOLERANCE

The epidemiological surveys and evidence-based medicine evidence indicated that IFG, IGT, and IFG + IGT populations have different incidences of diabetes and future cerebral and cardiovascular diseases. Based on this finding, experts divide prediabetes by blood glucose into three types: IFG, IGT, and IFG + IGT.

### Glycemic cutoff points for high-risk population for diabetes

#### Fasting plasma glucose: 5.6 mmol/L

For IFG screening, two Chinese studies in Chongqing and Shanghai (Class B evidence) have found FPG 5.6 mmol/L as the lower limit for Chinese IFG population.<sup>[5,6]</sup> As for IGT screening, a Chinese research (Class B evidence) supports FPG 5.6 mmol/L as a cutoff point while another follow-up survey (Class C evidence) indicates that when FPG  $\geq$ 5.6 mmol/L, incidence of major adverse cardiac events is rising.<sup>[7,8]</sup> For prediabetes screening, FPG 5.6 mmol/L has also been confirmed by several studies as an ideal cutoff point (Class A<sup>[9]</sup> and Class B evidence<sup>[10]</sup>).

#### Random plasma glucose: 7.8 mmol/L

An Indian, large-scale study focused on glucose level screening recommends RPG 7.8 mmol/L as a sensitive and specific cutoff point for diagnosis of diabetes (Class B evidence).<sup>[11]</sup>

Due to poor health knowledge in majority of the Chinese population, we believe the early recognition of prediabetic stages is critical. Thus, despite some contrary evidence, we

recommend an FPG cutoff value of 5.6 mmol/L as a more reasonable and suitable parameter in China.

## Atherosclerotic cerebrocardiovascular disease risk

Epidemiological evidence indicates that IFG increases the risk of stroke (Class B evidence).<sup>[12]</sup> However, correlation between IFG and cardiovascular diseases remains unclear.<sup>[13,14]</sup> IGT has been found to increase the risk of stroke in many studies.<sup>[15-18]</sup> Several meta-analyses have shown that incidence and risk of mortality of macrovascular diseases are highest in IFG + IGT prediabetic populations (Class B evidence) among prediabetics.<sup>[19,20]</sup> Although there are differences among these findings, most studies propose that IGT had higher risk than IFG.<sup>[21,22]</sup>

## Risk of progression to diabetes

Numerous studies have confirmed that the IFG + IGT prediabetic population has the highest risk of developing diabetes (Class B evidence).<sup>[16,19,23-25]</sup>

## Risk of microangiopathy

Many studies have demonstrated that microvascular diseases in the kidneys, retina, and nerves may occur in prediabetic patients (Class B evidence).<sup>[26-30]</sup>

## Risk of cancer

Prediabetic status is found to be an independent risk factor (Class B evidence) for deaths caused by cancer alone.<sup>[31-33]</sup> Studies have indicated that prediabetics with cancer have a significantly higher mortality rate than NGT patients.

## Other

A previous study involved long-term follow-up of individuals aged 75 years or over with neither mental intelligence decline nor full-blown diabetes. A 9-year follow-up showed that the adjusted risk ratio (95% confidence interval) of mental intelligence decline and Alzheimer's disease in seniors with borderline diabetes was 1.67 (1.04–2.67) and 1.77 (1.06–2.97), respectively (Class B evidence).<sup>[34]</sup>

## EVIDENCE SUPPORTING DRUG INTERVENTION

Although drug treatment increases the financial and psychological burden of prediabetics, long-term lifestyle intervention is very difficult to maintain. Oral administration is easy to perform and patients show relatively good compliance. It significantly decreases the incidence of diabetes and delays the progression of prediabetes to diabetes. It can also improve blood lipid levels, blood pressure, and other metabolic parameters and reduce the risk of ASCVD. Both the American Association of Clinical Endocrinologists and ADA recommend drug intervention when necessary.<sup>[24,35,36]</sup>

## Timing of initiating drug interventions

The ideal timing of initiating drug treatments for prediabetic individuals has yet to be established. There is an overseas recommendation that recommends pharmacological therapies to motivated individuals who cannot meet their

goals despite 6-month intensive lifestyle interventions.<sup>[37]</sup> Given the importance and urgency of antidiabetic therapy and the health and economic situation in China, the CSE consensus recommends drug intervention for prediabetic individuals who still cannot meet their glucose goals despite 6 months of intensive lifestyle modifications, given that these are young, motivated individuals who are otherwise with good financial status and healthcare accessibility. At the same time, physicians must adequately communicate with the prediabetics before initiating drug therapies.

## The influence of drug intervention on the incidence of diabetes

### Metformin

A study of the Indian Diabetes Prevention Program showed that metformin alone (500 mg b.i.d) or with intensive lifestyle intervention reduced the risk of diabetes (Class B evidence).<sup>[38]</sup> A previous study in China randomly divided IFG participants into placebo and metformin (0.25 g metformin 3 times daily) treatment groups. Follow-up lasted for 2 years. The results found that incidence of diabetes is 4.1% in the treatment group and 10.1% in the placebo group ( $P < 0.05$ ) (Class B evidence).<sup>[39]</sup> Another study of the American Diabetes Prevention Program randomly divided nondiabetic patients into three treatment groups, receiving placebo, metformin (850 mg, twice daily), and intensive lifestyle intervention. The incidence of T2DM in the metformin group reduced by 31%, and weight loss analysis showed that metformin treatment at 2550 mg/d had significant weight reduction ( $P < 0.01$ ) (Class A evidence).<sup>[40]</sup> A prospective diabetes study performed in the United Kingdom (UKPDS 34) and A Diabetes Outcome Progression Trial confirmed that large doses of metformin (2550 mg/d) could promote weight loss effectively (Class A evidence).<sup>[41,42]</sup> A recent study in China also confirmed that administration of 1500 mg metformin per day could also reduce body weight (MARCH) (Class A evidence).<sup>[43]</sup>

### Acarbose

A study of the impact of acarbose on T2DM was performed on an IGT population (STOP-NIDDM randomized trial: acarbose treatment group [highest dose of 100 mg tid, average 194 mg/d] and placebo group). Results showed that the cumulative incidence of T2DM patients decreased approximately 25% more in acarbose group than in control group ( $P = 0.0015$ ), and the same efficacy rates were recorded among the patients with high FPG and PPG.<sup>[44]</sup> Acarbose treatment also significantly reduced relative and absolute risks in hypertension ( $P = 0.005$ ), myocardial infarction ( $P = 0.002$ ), and any other cardiovascular disorders ( $P = 0.03$ ) (Class A evidence).<sup>[45]</sup> A study in China divided IGT patients into control group, diet and exercise group, acarbose group (50 mg tid), and metformin group (250 mg tid). Results showed that acarbose and metformin treatment groups reduced the incidence of

diabetes by 87.8% and 76.8%, respectively (Class B evidence).<sup>[46]</sup>

Another study concerning initial treatment of newly diagnosed T2DM from China (MARCH) demonstrated that patients given acarbose at 300 mg/d lost weight more efficiently than those given metformin at 1500 mg/d ( $P < 0.05$ ) (Class A evidence).<sup>[43]</sup>

### Thiazolidinedione

A Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medication randomized prediabetic patients into placebo and rosiglitazone groups (8 mg/d), with an average of 3-year follow-up. The results showed that rosiglitazone reduced the incidence of diabetes by 62%, and efficacy was similar in IFG, IGT, and IFG + IGT groups (Class A evidence).<sup>[47]</sup>

A study of pioglitazone called Actos Now or ACT NOW randomized IGT patients into different groups receiving either pioglitazone (starting dose of 30 mg/d, increased to 45 mg/d after 1 month) or placebo, with 2.4 years average follow-up. Results showed that the pioglitazone lowered incidence of diabetes by 72% (Class A evidence).<sup>[48]</sup>

### Other drugs

There have been similar studies on other drug regimens in prediabetic populations. However, considering long-term safety, efficacy, and health and economic benefits, these drugs have not been recommended by the experts in China.<sup>[36]</sup>

## CONCLUSION

The prevention of T2DM in Chinese adults, first, should involve screening high-risk populations. This would allow individuals to become aware of their condition early and facilitate early diagnosis and management of prediabetics, which is crucial for the prevention of diabetes. It can also delay the occurrence of ASCVD. In terms of intervention, CSE has emphasized lifestyle intervention as the cornerstone of preventive intervention. Large-scale clinical trials at home and abroad have proved that effective lifestyle intervention can decrease the incidence of diabetes, all-cause mortality, microvascular diseases, and cardiovascular mortality.<sup>[36,49-53]</sup> Its effectiveness is firmly supported by evidence-based medicine and it is also one of the safest and least expensive treatments. Therefore, pharmacological intervention should be the first choice. However, lifestyle changes can be very hard to implement and maintain, especially when persons have already cultivated their habits. For this reason, we recommend drug intervention for prediabetic individuals who have difficulty in making intensive lifestyle changes or those who still cannot meet their glucose goals despite 6 months of intensive lifestyle modifications, given that these are young, motivated individuals who are otherwise with good financial status and healthcare accessibility, especially IFG + IGT ones. All treatment regimens must be in compliance with the principle of individualization or personalization.

The consensus also emphasizes that the management of ASCVD risk factors should never be ignored; it can be as much as or even more important than glucose management.

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### Conflicts of interest

There are no conflicts of interest.

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